

CLAIMS

1. A medical prosthesis for use within the body, said prosthesis being formed of radiation treated ultra high molecular weight polyethylene having substantially no detectable free radicals.

2. The prosthesis of claim 1 wherein said radiation is selected from the group consisting of gamma radiation and electron radiation.

3. The prosthesis of claim 1 wherein said ultra high molecular weight polyethylene has a cross-linked structure, so as to reduce production of particles from said prosthesis during wear of said prosthesis.

4. The prosthesis of claim 1 wherein said ultra high molecular weight polyethylene is substantially not oxidized.

5. The prosthesis of claim 1 wherein said ultra high molecular weight polyethylene is substantially oxidation resistant.

6. The prosthesis of claim 1 wherein said ultra high molecular weight polyethylene has three melting peaks.

7. The prosthesis of claim 1 wherein said ultra high molecular weight polyethylene has two melting peaks.

8. The prosthesis of claim 1 wherein said ultra high molecular weight polyethylene has one melting peak.

9. The prosthesis of claim 1 wherein said polymeric structure has extensive cross-linking so that a substantial portion of said polymeric structure does not dissolve in xylene at 130°C or decalin at 150°C over a period of 24 hours.

10. The prosthesis of claim 1 wherein said ultra high molecular weight polyethylene has an initial average molecular weight of greater than about 2 million.

11. The prosthesis of claim 1 wherein part of said prosthesis is in the form of a cup or tray shaped article having a load bearing surface.

12. The prosthesis of claim 9 wherein said load bearing surface is in contact with a second part of said prosthesis having a mating load bearing surface of a metallic or ceramic material.

13. The prosthesis of claim 1 wherein said prosthesis is constructed and arranged for replacement of a joint selected from the group consisting of a hip joint, a knee joint, an elbow joint, a shoulder joint, an ankle joint and a finger joint.

14. The medical prosthesis of claim 1 wherein said ultra high molecular weight polyethylene has a polymeric structure with less than about 50% crystallinity, less than about 290 $\text{\AA}$  lamellar thickness and less than about 940 MPa tensile elastic modulus, so as to reduce production of fine particles from said prosthesis during wear of said prosthesis.

15. The prosthesis of claim 14 wherein said ultra high molecular weight polyethylene has a hardness of less than about 65 on the Shore D scale.

16. The prosthesis of claim 14 wherein said ultra high molecular weight polyethylene has a high density of entanglement so as to cause the formation of imperfect crystals and reduce crystallinity.

17. The prosthesis of claim 14 wherein said ultra high molecular weight polyethylene has a polymeric structure with about 40% crystallinity, about 100 $\text{\AA}$  lamellar thickness and about 200 MPa tensile elastic modulus.

18. Radiation treated ultra high molecular weight polyethylene having substantially no detectable free radicals.

19. The ultra high molecular weight polyethylene of claim 18 wherein said ultra high molecular weight polyethylene has a cross-linked structure.

20. The ultra high molecular weight polyethylene of claim 18 wherein said ultra high molecular weight polyethylene is substantially oxidation resistant.

21. The ultra high molecular weight polyethylene of claim 18 wherein said ultra high molecular weight polyethylene has three melting peaks.

22. The ultra high molecular weight polyethylene of claim 18 wherein said ultra high molecular weight polyethylene has two melting peaks.

23. The ultra high molecular weight polyethylene of claim 18 wherein said ultra high molecular weight polyethylene has one melting peak.

24. The ultra high molecular weight polyethylene of claim 18 wherein said ultra high molecular weight polyethylene has a unique polymeric structure characterized by less than about 50% crystallinity, less than about 290 $\text{\AA}$  lamellar thickness and less than about 940 MPa tensile elastic modulus.

25. The ultra high molecular weight polyethylene of claim 24 wherein said ultra high molecular weight polyethylene has high transmissivity of light.

26. The ultra high molecular weight polyethylene of claim 24 wherein said ultra high molecular weight polyethylene is a film or sheet, said film or sheet being transparent and wear resistant.

27. A fabricated article formed of radiation treated ultra high molecular weight polyethylene having substantially no detectable free radicals.

28. The fabricated article of claim 26 wherein said ultra high molecular weight polyethylene has a cross-linked structure.

29. The fabricated article of claim 26 wherein said ultra high molecular weight polyethylene is substantially oxidation resistant.

30. The fabricated article of claim 27 wherein said ultra high molecular weight polyethylene has three melting peaks.

31. The fabricated article of claim 27 wherein said ultra high molecular weight polyethylene has two melting peaks.

32. The fabricated article of claim 27 wherein said ultra high molecular weight polyethylene has one melting peak.

33. The fabricated article of claim 27 wherein said fabricated article is in the form of a bar stock capable of being shaped into a second article by machining.

34. The fabricated article of claim 27 wherein said fabricated article has a load bearing surface.

35. The fabricated article of claim 27 wherein said ultra high molecular weight polyethylene has a polymeric structure with less than about 50% crystallinity, less than about 290Å lamellar thickness and less than about 940 MPa tensile elastic modulus.

36. A method for making a cross-linked ultra high molecular weight polyethylene having substantially no detectable free radicals, comprising the steps of:

providing conventional ultra high molecular weight polyethylene having polymeric chains;

irradiating said ultra high molecular weight polyethylene so as to cross-link said polymeric chains;

heating said irradiated ultra high molecular weight polyethylene above the melting temperature of said ultra high molecular weight polyethylene so that there are substantially no detectable free radicals in said ultra high molecular weight polyethylene; and

cooling said heated ultra high molecular weight polyethylene to room temperature.

37. The method of claim 36 further comprising the step of machining said cooled ultra high molecular weight polyethylene.

38. The method of claim 37 further comprising the step of sterilizing said machined ultra high molecular weight polyethylene.

39. The method of claim 36 wherein said ultra high molecular weight polyethylene in said providing step is selected from the group consisting of a bar stock, a shaped bar stock, a coating and a fabricated article.

40. The method of claim 36 wherein said ultra high molecular weight polyethylene in said providing step is a cup or tray shaped article for use in a prosthesis.

41. The method of claim 36 wherein said ultra high molecular weight polyethylene in said providing step is machined bar stock.

42. The method of claim 36 wherein said ultra high molecular weight polyethylene in said providing step has an initial average molecular weight of greater than about 2 million.

43. The method of claim 36 wherein said ultra high molecular weight polyethylene in said providing step is pre-heated to a temperature below the melting temperature of said ultra high molecular weight polyethylene.

44. The method of claim 43 wherein said pre-heated temperature of said ultra high molecular weight polyethylene is about 20°C to about 135°C.

45. The method of claim 43 wherein said pre-heated temperature of said ultra high molecular weight polyethylene is about 50°C.

46. The method of claim 43 wherein said pre-heating is done in a non-inert environment.

47. The method of claim 43 wherein said pre-heating is done in an inert environment.

48. The method of claim 43 wherein the irradiation is by electron irradiation and the dose rate from said irradiation is about 0.05 to about 10 Mrad/minute.

49. The method of claim 43 wherein the irradiation is by electron irradiation and the dose rate from said irradiation is about 4 to about 5 Mrad/minute.

50. The method of claim 43 wherein the irradiation is by gamma irradiation and the dose rate from said irradiation is about 0.05 to about 0.2 Mrad/minute.

51. The method of claim 43 wherein said irradiating step is done in an inert environment.

52. The method of claim 43 wherein said irradiating step is done in a non-inert environment.

53. The method of claim 43 wherein said ultra high molecular weight polyethylene in said providing step is in an insulating material so as to reduce heat loss from said UHMWPE during processing.

54. The method of claim 43 wherein said pre-heated temperature of said ultra high molecular weight polyethylene prior to said irradiating step is about 100°C to about 135°C.

55. The method of claim 43 wherein said pre-heated temperature of said ultra high molecular weight polyethylene prior to the irradiating step is about 120°C.

56. The method of claim 43 wherein the final temperature of said ultra high molecular weight polyethylene after said heating step is above the melting temperature of said ultra high molecular weight polyethylene.

57. The method of claim 56 wherein said final temperature is about 140°C to about 200°C.

58. The method of claim 56 wherein said final temperature is about 145°C to about 190°C.

59. The method of claim 56 wherein said final temperature is about 150°C.

60. The method of claim 43 wherein said irradiating step uses electron irradiation so as to generate adiabatic heating.

61. The method of claim 60 wherein said heating of said irradiated ultra high molecular weight polyethylene step results from said adiabatic heating.

62. The method of claim 61 further comprising additionally heating said irradiated ultra high molecular weight polyethylene subsequent to said adiabatic heating so that the final temperature of said ultra high molecular weight polyethylene after said additional heating is above the melting temperature of said ultra high molecular weight polyethylene.

63. The method of claim 62 wherein said final temperature of said ultra high molecular weight polyethylene after said additional heating is about 140°C to about 200°C.

64. The method of claim 62 wherein said final temperature of said ultra high molecular weight polyethylene after said additional heating is about 145°C to about 190°C.

65. The method of claim 62 wherein said final temperature of said ultra high molecular weight polyethylene after said additional heating is about 150°C.

66. The method of claim 60 wherein the dose rate of said electron irradiation is about 2 to about 3,000 Mrad/minute.

67. The method of claim 60 wherein the dose rate of said electron irradiation is about 7 to about 25 Mrad/minute.

68. The method of claim 60 wherein the dose rate of said electron irradiation is about 7 Mrad/minute.

69. The method of claim 60 wherein the total absorbed dose of said electron irradiation is about 1 to about 100 Mrad.

70. The method of claim 60 wherein the total absorbed dose of said electron irradiation is about 22 Mrad.

71. The method of claim 36 wherein said ultra high molecular weight polyethylene in said providing step is at room temperature or below room temperature.

72. The method of claim 71 wherein said irradiating step uses electron irradiation so as to generate adiabatic heating.

73. The method of claim 72 wherein said heating of said irradiated ultra high molecular weight polyethylene results from said adiabatic heating.

74. The method of claim 73 further comprising additionally heating said irradiated ultra high molecular weight polyethylene subsequent to said adiabatic heating so that the final temperature of said ultra high molecular weight polyethylene after said additional heating is above the melting temperature of said ultra high molecular weight polyethylene.

75. The method of claim 36 wherein said irradiating step is done in a non-inert environment.

76. The method of claim 36 wherein said irradiating step is done in an inert environment.

77. The method of claim 36 wherein said irradiating step uses irradiation selected from the group consisting of gamma irradiation and electron irradiation.

78. The method of claim 36 wherein said irradiating step is at a dose rate that does not generate enough heat to melt said ultra high molecular weight polyethylene.

79. The method of claim 36 wherein said irradiating step uses gamma irradiation and the dose rate of said gamma irradiation is about 0.005 to about 0.2 Mrad/minute.

80. The method of claim 36 wherein said irradiating step uses electron irradiation and the dose rate of said electron irradiation is about 0.05 to about 3,000 Mrad/minute.

81. The method of claim 36 wherein the dose rate from said irradiating step is about 0.05 to about 5 Mrad/minute.

82. The method of claim 36 wherein said irradiating step uses electron irradiation and the energy of the electrons is about 0.5 MeV to about 12 MeV.

83. The method of claim 36 wherein the total absorbed dose of said irradiation is about 0.5 to about 1,000 Mrad.

84. The method of claim 36 wherein the total absorbed dose of said irradiation is about 1 to about 100 Mrad.

85. The method of claim 36 wherein the total absorbed dose of said irradiation is about 4 to about 30 Mrad.

86. The method of claim 36 wherein the total absorbed dose of said irradiation is about 20 Mrad.

87. The method of claim 36 wherein the total absorbed dose of said irradiation is about 15 Mrad.

88. The method of claim 36 wherein said temperature in said heating step is about 137°C to about 300°C.

89. The method of claim 36 wherein said temperature in said heating step is about 140°C to about 300°C.

90. The method of claim 36 wherein said temperature in said heating step is about 145°C to about 300°C.

91. The method of claim 36 wherein said temperature in said heating step is about 140°C to about 190°C.

92. The method of claim 36 wherein said temperature in said heating step is about 145°C to about 190°C.

93. The method of claim 36 wherein said temperature in said heating step is about 150°C.

94. The method of claim 36 wherein said temperature in said heating step is maintained for about 0.5 minutes to about 24 hours.

95. The method of claim 36 wherein said temperature in said heating step is maintained for about 1 hour to about 3 hours.

96. The method of claim 36 wherein said heating step is performed in an environment selected from the group consisting of air, an inert gas, a sensitizing atmosphere and a vacuum.

97. The method of claim 36 wherein said cooling step is at a rate greater than about 0.1°C/minute.

98. The product made in accordance with claim 36.

99. A method for making crosslinked ultra high molecular weight polyethylene, comprising the steps of:

providing conventional ultra high molecular weight polyethylene;

heating said ultra high molecular weight polyethylene above the melting temperature of said ultra high molecular weight polyethylene so as to completely melt all crystalline structure of said ultra high molecular weight polyethylene;

irradiating said heated ultra high molecular weight polyethylene; and

cooling said irradiated ultra high molecular weight polyethylene to about 25°C.

100. The method of claim 99 further comprising surrounding said ultra high molecular weight polyethylene with an inert material that is substantially free of oxygen.

101. The method of claim 99 wherein said cooled irradiated ultra high molecular weight polyethylene has substantially no detectable free radicals.

102. The method of claim 99 wherein said ultra high molecular weight polyethylene in said providing step is selected from the group consisting of a bar stock, a shaped bar stock, a coating and a fabricated article.

103. The method of claim 99 wherein said ultra high molecular weight polyethylene in said providing step is a cup or tray shaped article for use in a prosthesis.

104. The method of claim 99 wherein said ultra high molecular weight polyethylene in said providing step is machined bar stock.

105. The method of claim 99 wherein said ultra high molecular weight polyethylene in said providing step has an initial average molecular weight of greater than about 2 million.

106. The method of claim 99 wherein said temperature in said heating step is about 145°C to about 230°C.

107. The method of claim 99 wherein said temperature in said heating step is about 175°C to about 200°C.

108. The method of claim 99 wherein said temperature in said heating step is maintained for about 5 minutes to about 3 hours.

109. The method of claim 99 wherein said irradiating step uses irradiation selected from the group consisting of gamma irradiation and electron irradiation.

110. The method of claim 99 wherein said irradiating step delivers a dose of greater than about 1 MRad to said heated ultra high molecular weight polyethylene.

111. The method of claim 99 wherein said cooling step is at a rate greater than about 0.5°C/min.

112. The method of claim 99 further comprising the step of machining said cooled ultra high molecular weight polyethylene.

113. The product made in accordance with claim 99.

114. A method for making highly entangled and crosslinked ultra high molecular weight polyethylene, comprising the steps of:

providing conventional ultra high molecular weight polyethylene;

heating said ultra high molecular weight polyethylene above the melting temperature of said ultra high molecular weight polyethylene for a time sufficient to enable the formation of

entangled polymer chains in said ultra high molecular weight polyethylene;

irradiating said heated ultra high molecular weight polyethylene so as to trap the polymer chains in the entangled state; and

cooling said irradiated ultra high molecular weight polyethylene to about 25°C.

115. The method of claim 114 further comprising surrounding said ultra high molecular weight polyethylene with an inert material that is substantially free of oxygen.

116. The product made in accordance with claim 114.

117. A method of making a medical prosthesis from radiation treated ultra high molecular weight polyethylene having substantially no detectable free radicals, said prosthesis resulting in the reduced production of particles from said prosthesis during wear of said prosthesis, comprising the steps of:

providing radiation treated ultra high molecular weight polyethylene having no detectable free radicals; and

forming a medical prosthesis from said ultra high molecular weight polyethylene so as to reduce production of particles from said prosthesis during wear of said prosthesis, said ultra high molecular weight polyethylene forming a load bearing surface of said prosthesis.

118. The method of claim 117 wherein said ultra high molecular weight polyethylene has a polymeric structure with less than about 50% crystallinity, less than about 290 $\text{\AA}$  lamellar thickness and less than about 940 MPa tensile elastic modulus.

119. A method of treating a body in need of a medical prosthesis, comprising:

providing a shaped medical prosthesis formed of radiation treated ultra high molecular weight polyethylene having substantially no detectable free radicals; and

applying said prosthesis to said body in need of said prosthesis.

120. The method of claim 119 wherein said ultra high molecular weight polyethylene has a polymeric structure with less than about 50% crystallinity, less than about 290 $\text{\AA}$  lamellar thickness and less than about 940 MPa tensile elastic modulus.

121. The method of claim 119 wherein said ultra high molecular weight polyethylene has three melting peaks.

122. The method of claim 119 wherein said ultra high molecular weight polyethylene has two melting peaks.

123. The method of claim 119 wherein said ultra high molecular weight polyethylene has one melting peak.